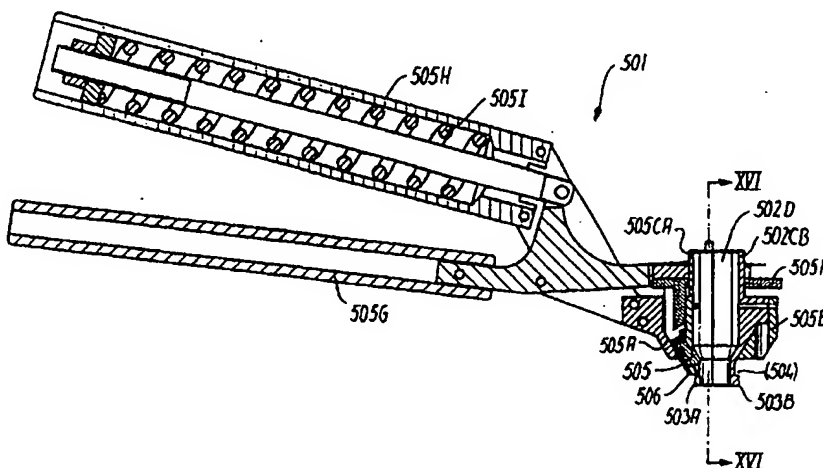


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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: METHOD AND ANASTOMOTIC INSTRUMENT FOR USE WHEN PERFORMING AN END-TO-SIDE ANASTOMOSIS



## (57) Abstract

In a method of establishing an end-to-side anastomosis by using an instrument (501) with a passage (502D) for a bypass vessel, terminated by a circumferential anvil (502A, 503B), about which the end of the bypass vessel may be everted and then inserted through an anastomosis opening in a second vessel, such as a coronary artery, after which the tissue edges to be joined are first clamped together by clamping slides (505) and then stapled together by stapling plungers (506) so as to interconnect the two vessels, the main novel feature is that the stapling plungers (506) are arranged to move at an angle to the passage (502D) instead of parallel to it. With this arrangement, it is possible to use a greater number of staples than has been possible in previous related methods. Preferably also, the instrument is adapted to be divided lengthwise of the passage (502D).

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METHOD AND ANASTOMOTIC INSTRUMENT FOR USE WHEN PERFORMING  
AN END-TO-SIDE ANASTOMOSIS

TECHNICAL FIELD

5

The present invention relates to a method of the kind set forth in the preamble of claim 1.

BACKGROUND ART

10

A method of this kind is described in the international application PCT/DK95/00430. In this previous method, the stapling plungers as well as the associated clamping members were adapted to move in directions substantially parallel to the passage, in which the graft vessel was placed in readiness for establishing an end-to-side anastomosis with e.g. a coronary artery. With such an arrangement, the number of staples as well as their mutual closeness were limited by the purely mechanical need for guiding the stapling plungers in their operative movement, with the result that in the "seam" connecting the two vessels, there could be substantial distances between adjacent staples.

25

DISCLOSURE OF THE INVENTION

It is the object of the present invention to provide a method of the kind referred to above, with which it is possible to use the instrument for establishing anastomoses with a greater number of staples and with smaller distances between adjacent staples than has been possible with the previously known method referred to above. This object is achieved by proceeding as set forth

30

in the characterizing clause of claim 1. In this manner, the guideways for the stapling plungers will mostly be situated at a greater "radius" than the staple-bending recesses, so that there is ample space for forming these  
5 guideways in a greater number than previously, to converge at very small mutual distances at the staple-bending recesses in the anvil.

The present invention also relates to an anastomotic  
10 instrument for carrying out the method according to the invention, and this instrument is characterized by the features set forth in claim 4.

Advantageous embodiments of the method and the anastomotic  
15 instrument according to the invention, the effects of which - beyond what is self-evident - are explained in the following detailed part of the present description, are set forth in claims 2, 3 and 5-7, respectively.

## 20 BRIEF DESCRIPTION OF THE DRAWINGS

In the following detailed part of the present description, the invention will be explained in more detail with reference to the exemplary embodiments of an anastomotic  
25 instrument according to the invention shown in the drawings, in which

Figures 1-8 show the process of performing an end-to-side anastomosis using an anastomotic instrument  
30 according to the invention subject of the application PCT/DK95/00430 referred to initially, Figures 1-7 being drawn in a highly simplified manner for ease of understanding,

Figures 9-11 in perspective and with certain parts cut away show a practical embodiment of an anastomotic instrument according to the present invention with the various possible relative positions of the relatively movable parts,

Figures 12-14 are side views of a staple-pusher set consisting of a stapling plunger, a clamping slide and their common operating slide in positions corresponding to those shown in Figure 9-11, respectively.

Figure 15 is a sectional side view of the complete instrument,

Figure 16 is a sectional view taken along the line XVI-XVI in Figure 15,

Figures 17-19 show a core member with associated anvil tube as viewed from the rear, side and front, respectively, and

Figures 20-22 show a housing likewise as viewed from the rear, side and front, respectively.

Please note that the "front end" of the instrument is the end comprising the part in operation being in contact with the anastomosis being established, in this case the anvil 503A, 503B.

30

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

As mentioned above, the embodiment shown in Figures 1-8 of the anastomosis instrument according to the invention

subject of the application PCT/DK95/00430 constitutes a simplified version with the primary purpose of explaining the invention; this does not, however, preclude the possibility of using this embodiment in actual practice.

5

Thus, Figure 1 shows an anastomosis instrument 1 consisting of three main components that are movable relative to each other in the longitudinal direction, i.e. in the direction shown as the vertical direction in Figure 1:

10

- an anvil tube 2,
- a clamping tube 5, and
- a set of stapling plungers 6.

15

On its lower end, the anvil tube 2 carries an anvil 3, the upper side of which is provided with a number of staple-bending recesses 4 adapted to cooperate with and bend an equal number of staples 7, in the situation shown in Figure 1 being temporarily held lightly in an equal number of staple-holding recesses 8 formed in the lower ends of the stapling plungers 6.

20

Figure 2 shows the situation, in which the instrument is made ready for use by the operating surgeon. As mentioned initially, the anastomosis instrument shown is primarily developed for use when performing coronary bypass operations, and to this end, a bypass vessel 9 - that may be a vein taken from some other part of the patient's body - has been inserted in the anvil tube with its lower end everted about the anvil 3 and with its end region 10 covering the staple-bending recesses 4 in the upper surface of the anvil 3. At this point it should be noted that the bypass vessel 9 may have a considerably larger circumference than the inside of the anvil tube 2,

25

30

consequently lying more or less folded in the longitudinal direction in the latter, for which reason the action of everting its end region 10 about the anvil 3 does not necessarily entail undue stretching of the bypass vessel 9.

Figure 3 shows the instrument having been made ready as shown in Figure 2 inserted in an opening in a coronary artery 11, said opening having an edge region 12 which, due to the elasticity of the tissue of the coronary artery 11, will embrace the anvil tube 2 in a location close to the anvil 3. The opening in the coronary artery 11 may e.g. have been formed according to the method described in the international application with publication No. WO 95/17127 with the title "Method and instrument for establishing the receiving side of a coronary artery bypass graft".

As soon as the operating surgeon in the situation shown in Figure 3 has ascertained that the edge region 12 embraces the anvil tube 2 closely on all sides, he or she will proceed to the situation shown in Figure 4, in which the clamping tube 5 has been moved towards the anvil 3 so as to clamp the edge region 12 on the coronary artery 11 and the end region 10 on the bypass vessel 9 firmly together in readiness for the next step shown in Figure 5, in which the stapling plungers 6 have been moved downwardly so as to cause the staples 7 to penetrate the edge region 12 and the end region 10 and engage the staple-bending recesses 4, by which they will be bent inwards in a tangential direction in a similar manner to what is known from both surgical staplers and ordinary office staplers.

In the situation shown in Figure 6, the clamping tube 5 together with the stapling plungers 6 have been moved outwardly and away from the staples 7, the staple-holding recesses 8 due to their light holding action having let go of the staples 7, the latter also having been anchored in the end region 10 by their bent ends.

Figure 7 shows the situation, in which the operation of removing the anastomosis instrument 1 from the coronary artery 11 and its anastomosis with the bypass vessel 9 has begun. As will be seen from Figures 6 and 7, the circumferential pocket formed by the eversion of the lower end of the bypass vessel 9 will now open and allow the anvil 3 to be removed by luxation, Figure 8 showing the situation after such removal, resulting in a finished anastomosis of the intima-to-intima type considered most desirable for this type of operation.

The three main components of the anastomosis instrument 1 referred to above, i.e. the anvil tube 2, the clamping tube 5 and the set of stapling plungers 6, will, of course, have to be connected to some kind of operating members to enable the operating surgeon and his or her assistants to carry out the steps shown in Figures 1-8. Theoretically, these operating members could consist of three tubes (not shown), viz.

- a relatively long holding tube in continuation of the anvil tube 2,
- a somewhat shorter clamping tube in continuation of the clamping tube 5, and
- an even shorter stapling tube, to which the stapling plungers 6 are connected.

As is well-known, however, coronary bypass operations,



especially according to the method subject to the international application No. WO 95/17127 entitled "Method and instrument for establishing the receiving site of a coronary artery bypass graft", should be carried out as rapidly as possible, and for this reason, the "theoretical" embodiment shown in Figures 1-7 is too cumbersome to work with to ensure a sufficiently rapid operating procedure. As mentioned above, Figures 9-22 illustrate an embodiment of an anastomosis instrument according to the present invention, that is highly suitable for creating an end-to-side anastomosis in a very short time.

In Figures 9-22, those of the components functionally corresponding to components shown in Figures 1-7 have been given the same reference numbers with 500 added, whereas components not having "opposite numbers" in Figures 1-7 have been given the reference numbers of the components, with which they are most closely related, with the addition of a capital letter.

As shown in Figure 9, the anastomosis instrument 501 comprises a number of parts functionally related to parts of the instrument shown in Figures 1-7, viz.:

- an anvil tube 502A, 502B,
- an anvil 503A, 503B,
- a set of clamping slides 505, slidable in
- a clamping-slide housing 505A, 505B, and
- a set of stapling plungers 506 slidable in said clamping slides 505.

Although the basic functions of these parts are the same as the basic functions of related parts in the embodiment of Figures 1-7, the arrangement differs somewhat from

that of the latter, as will be evident from the following.

Thus, the anvil tube 502A, 502B of Figure 9 is an extension of a core member 502CA, 502CB, cf. also Figure 15, a central passage 502D extending all the way through both the core member 502CA, 502CB and the anvil tube 502A, 502B so as to make it possible to place a bypass vessel in the passage in the same manner as shown in Figure 2, showing a bypass vessel 9 placed in the anvil tube 2.

The rear face of the anvil 503A, 503B, facing upwardly in Figure 9, is provided with a number of staple-bending recesses 504 substantially evenly distributed about the anvil and each adapted to co-operate with a respective one of the stapling plungers 506.

The clamping slides 505 are adapted to slide in a direction making an angle of substantially 30° with the longitudinal axis of the passage 502D, being guided for such movement by guideways formed in the inside of the slide housing 505A, 505B and in the outside of the core member 502CA, 502CB.

Similarly, each of the stapling plungers 506 is adapted to slide in substantially the same direction in a guideway in a respective one of the clamping slides 505. Both the clamping slides 505 and the stapling plungers 506 are provided with short operating studs 505C and 506C, respectively, for co-operation with angular operating slots 505D formed in operating slides 505E adapted to slide in guideways formed in the inside of the slide housing 505A, 505B and in the outside of the core member 502CA, 502CB in a direction substantially parallel to the longitudinal

axis of the passage 502D.

5 All the operating slides 505E are connected to a common operating head 505F, the latter in turn being connected to one arm 505G of a pair of tongs 505G, 505H adapted to be operated manually by the surgeon, the other arm 505H being connected to the core member 502A, 502B and the clamping-slide housing 505A, 505B.

10 When an anastomosis is to be established according to the principles explained above with reference to Figures 1-8, the first step is, with the mutually movable parts in the positions shown in Figures 9 and 12 and with the stapling plungers 506 "loaded" with staples (not shown),  
15 to place a bypass vessel in the passage 502D and evert its forward (lower) end about the anvil 503A, 503B in the manner shown in Figure 2. The next step is to insert the anvil 503A, 503B with the everted end of the bypass vessel into an opening formed in the side of, say, a coronary artery in the manner shown in Figure 3. These two  
20 steps are suitably carried out using the pair of tongs 505G, 505H as a "handle".

25 When the surgeon has ascertained that the bypass vessel is in the correct position relative to the artery, she or he will press the arm 505G towards the arm 505H, thus causing the common operating head 505F to move the operating slides 505E forward (downward), vide Figures 10 and 13, so as to bring the clamping slides 505, moved by  
30 the co-operation between the oblique parts of the operating slots 505D and the operating studs 505C, close to the rear (upper) face of the anvil 503A, 503B, thus creating a situation analogous to that shown in Figure 4. At this point it should, however, be noted that the ob-

lique forward (downward) and inward movement of the clamping slides cause their forward end to exert a certain inwardly directed force on the tissues thus being clamped, thus counteracting any tendency for these tissues to slip off from the anvil.

Continued movement of the arm 505G towards the "stationary" arm 505H will, of course, create further forward (downward) movement of the operating slides 505E, vide Figures 11 and 14. The in-line parts of the operating slots 505D will now hold the clamping slides 505 in a clamping position, holding the tissues to be joined in the same manner as shown in Figure 4, while the final part of the movement will cause the oblique parts of the operating slots 505D to advance the stapling plungers 506 and cause the latter to insert the staples (not shown) and bend them in co-operation (in contact) with the staple-bending recesses 504 in the same manner as shown in Figure 5. All of these recesses are (of course) placed at an outwardly directed angle of same substantially 30°.

At this point, the anastomosis has been established, after which the instrument can be removed according to the principles illustrated by Figures 6-8, the surgeon previously having released the pressure on the arm 505G, allowing the spring 505I to act in the opposite direction, causing the parts 506, 505, 505E and 505F to return to the positions shown in Figure 9. If the core member 502CA, 502CB and the clamping slide housing 505A, 505B were unitary components, i.e. each made in one piece, this removal would have to be effected by pulling the instrument away from the anastomosis towards the free end of the bypass vessel (not shown). One prerequisite for so doing is, obviously, that such a free end exists, i.e.

that the bypass vessel is not part of an anastomosis at the other end.

5 In order to make it possible to remove the instrument from a bypass vessel without a free end, the components surrounding it, i.e. surrounding the passage 502D, are constituted by downstream parts 502CA, 505A and 503A and upstream parts 502CB, 505B and 503B, respectively of the core member, the clamping-slide housing and the anvil, 10 respectively. (The expressions "upstream" and "downstream" refer to the direction of flow in the coronary artery being operated upon when the instrument is placed in the preferred orientation relative to the artery, i.e. with the blood flowing towards the left in Figure 15).

15 The upstream part 505B of the housing 505A, 505B is releasably connected to the downstream part 505A by means of hook-and-pin connections, cf. Figures 9, 16 and 21, constituted by recesses 505AB in the downstream part 505A adapted to receive projections 505BB on the upstream 20 part, holding slots 505AC and 505BC being formed in alignment with the recesses 505AB and the projections 505BB, respectively, and adapted to receive removable holding pins 505K.

25 When the core member 502CA, 502CB and the clamping-slide housing 505A, 505B are assembled with the holding pins 505K in place as shown in Figures 9 and 16, the housing 505A, 505B will keep the core member 502CA, 502CB from coming apart. Conversely, when the holding pins 505K 30 have been pulled up, both the housing 505A, 505B and the core member 502CA, 502CB can easily be divided by simply pulling them apart, thus making it possible to remove the apparatus from the bypass vessel in a lateral direc-

tion. During this operation of dividing the core member and the housing, the various parts associated with them will, of course, have to be divided or liberated. The means for achieving this are not shown in detail, as any  
5 normally skilled mechanical technician or toolmaker should be able to devise the requisite mechanism without further guidance from the present description.

LIST OF PARTS

	1	anastomosis instrument
	2	anvil tube
5	3	anvil
	4	staple-bending recess
	5	clamping tube
	6	stapling plunger
	7	staple
10	8	staple-holding recess
	9	bypass vessel
	10	end region
	11	coronary artery
	12	edge region
15	13	fin or finger
	501	anastomosis instrument
	502A,B	anvil tube
	502CA,CB	core member
20	502D	central passage
	503A,B	anvil
	504	staple-bending recess
	505	clamping slide (and stapling-plunger guide)
	505A,B	clamping-slide housing
25	505AB	recess
	505AC	slot
	505BB	projection
	505BC	slot
	505C	clamping-slide operating stud
30	505D	operating slot
	505E	operating slide
	505F	common operating head
	505G	arm )
	505H	arm ) pair of tongs

505I	spring
505K	holding pin
506	stapling plunger
506C	stapling-plunger operating stud



CLAIMS

1. Method of connecting an end region (10) of a first vessel (9) to the side of a second vessel (11) by carrying out an end-to-side anastomosis, said method being of the kind comprising the following steps a-d:
- 5 a) forming an opening in the side of said second vessel (11),
- b) inserting in said opening an anastomosis instrument (501) carrying said first vessel (9) in a longitudinal cavity (502D) and with said end region (10) everted about a circumferential member (503A, 503B) constituting a forward portion of said instrument (501) in such a manner, that the intima side of said end region (10) comes into contact with the intima side of said second vessel (11) at an edge region (12) of said opening,
- 10 c) joining said end region (10) to said edge region (12) by inserting penetratingly therethrough and leaving therein a plurality of spiked members, and
- 15 d) removing said instrument (501) from the joint formed between said first (9) and second (11) vessels,
- 20 said steps a-d being carried out by
- e) the use of an anastomosis instrument (501) comprising
- e1) an anvil assembly (502A, 502B, 503A, 503B) comprising a circumferential anvil member (503A, 503B) and in which said first vessel (9) may be placed with its end region (10) everted about said anvil member (503A, 503B) with the terminal part of said end region facing rearwardly,
- 25 e2) rearwardly facing staple-bending recesses (504)
- 30

- e3) provided in said anvil member (503A, 503B),  
clamping members (505) adapted to be moved  
towards said anvil member (503A, 503B) so as to  
make it possible to clamp together therebetween  
said end region (10) on said first vessel (9)  
and an edge region (12) on said second vessel  
(11), and
- e4) stapling plungers (506) movable relative to  
said anvil member and adapted to insert staples  
penetratingly through said clamped end (10)  
and edge (12) regions into engagement with  
said stapling-bending recesses (504) so as to  
bend permanently said staples into a shape, in  
which they hold said end (10) and edge (12)  
regions together,

characterized by

- f) the use of an instrument (501), in which said  
stapling plungers (506) are slidable in direc-  
tions forming acute angles with the longitudinal  
axis of said longitudinal cavity (502D) and  
converging in a region forward of said circum-  
ferential anvil member (503A, 503B).

2. Method according to claim 1, characterized by  
the use of an instrument (501), in which said clamping  
members (505) are slidable in directions parallel to  
those, in which adjacent ones of said stapling plungers  
(506) are slidable.

3. Method according to claim 1 or 2, characterized  
by the use of an instrument (501), in which parts (502CA,  
502CB, 503A, 503B, 505A, 505B) surrounding said passage  
(502D) are releasably interconnected (505AB, 505BB, 505AC,  
505BC, 505K) so as to enable said passage (502D) to be

split lengthwise.

4.           Anastomotic instrument (501) for carrying out the method of any one or any of the claims 1-3 and of the kind comprising
- 5           a)           an anvil assembly (502A, 502B, 503A, 503B) comprising a circumferential anvil member (503A, 503B) and in which said first vessel (9) may be placed with its end region (10) everted about said anvil member (503A, 503B) with the terminal part of said end region facing rearwardly,
- 10           b)           rearwardly facing staple-bending recesses (504) provided in said anvil member (503A, 503B),
- c)           clamping members (505) adapted to be moved towards said anvil member (503A, 503B) so as to make it possible to clamp together therebetween said end region (10) on said first vessel (9) and an edge region (12) on said second vessel (11), and
- 15           d)           stapling plungers (506) movable relative to said anvil member and adapted to insert staples penetratingly through said clamped end (10) and edge (12) regions into engagement with said stapling-bending recesses (504) so as to bend permanently said staples into a shape, in which they hold said end (10) and edge (12) regions together,
- 20           e)           that said stapling plungers (506) are slidable in directions forming acute angles with the longitudinal axis of said longitudinal cavity (502D) and converging in a region forward of said circumferential anvil member (503A, 503B).
- 25           characterized in
- 30           e)           that said stapling plungers (506) are slidable in directions forming acute angles with the longitudinal axis of said longitudinal cavity (502D) and converging in a region forward of said circumferential anvil member (503A, 503B).

5. Instrument (501) according to claim 4, characterized in that said clamping members (505) are slidable in directions parallel to those, in which adjacent ones of said stapling plungers (506) are slidable.

5

6. Instrument (501) according to claim 4 or 5, characterized in that parts (502CA, 502CB, 503A, 503B, 505A, 505B) surrounding said passage (502D) are releasably interconnected (505AB, 505BB, 505AC, 505BC, 505K) so as to enable said passage (502D) to be split lengthwise.

10

7. Instrument (501) according to claim 5 or 6, characterized in

- 15 a) that said clamping members (505) are provided with first laterally extending operating studs (505C),
- b) that said stapling plungers (506) are provided with second laterally extending operating studs (506C), and
- 20 c) that said first (505C) and second (506C) operating studs are adapted to co-operate with common angular operating slots (505D) in likewise common operating slides (505E) adapted to be operated by a manually operable mechanism (505F, 505G, 505H, 505I) common to all operating slides (505E), all in such a manner, that
- 25 c1) in an initial phase of movement of said operating slides (505E) (Figures 9 and 12 to Figures 10 and 13), the clamping members (505) move into close adjacency to said anvil member (503A, 503B), and
- 30 c2) in a final phase of movement of said operating slides (505E) (Figures 10 and 13 to Figures 11 and 14), the stapling plungers (506) move into

a staple-bending position close to said anvil member (503A, 503B).

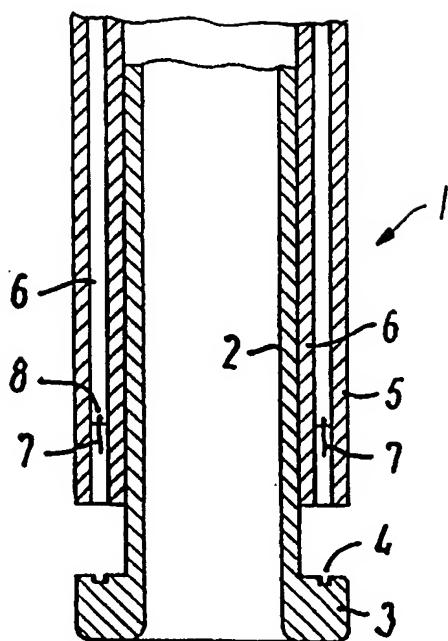


FIG. 1

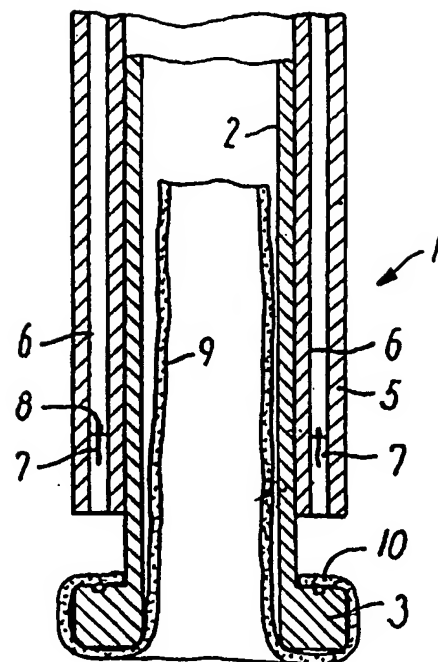


FIG. 2

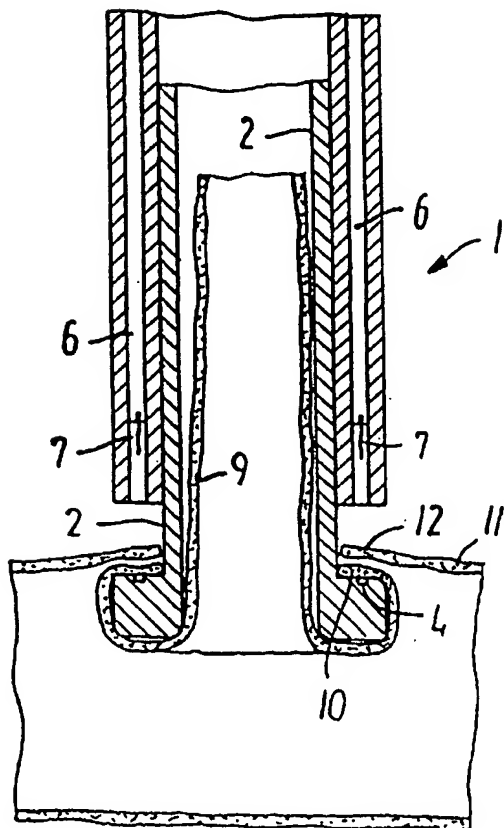


FIG. 3

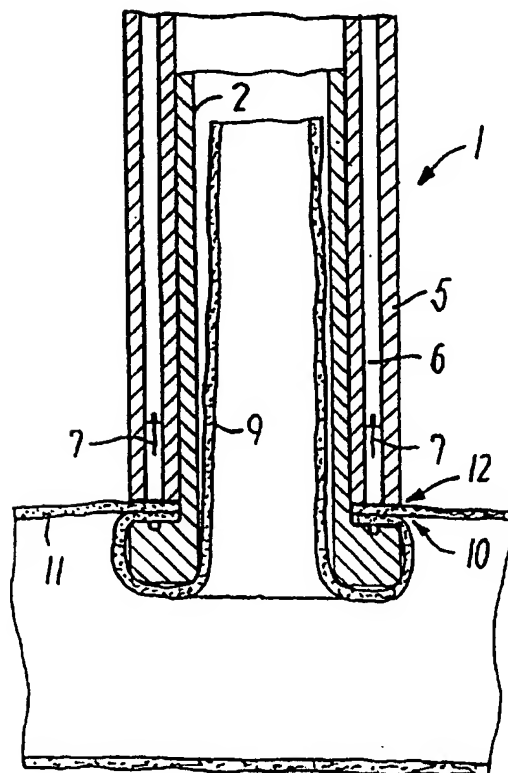


FIG. 4

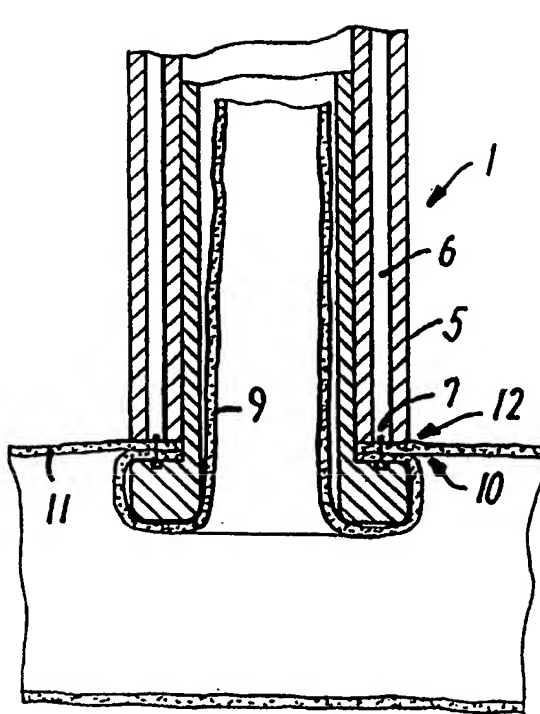


FIG. 5

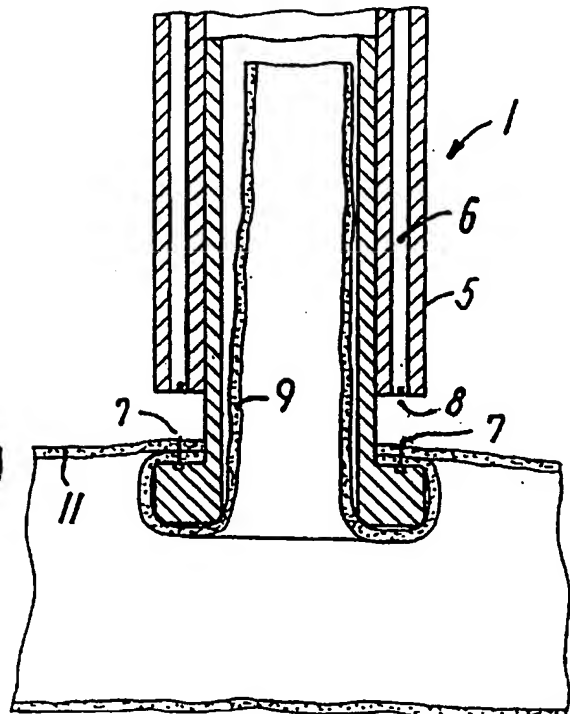


FIG. 6

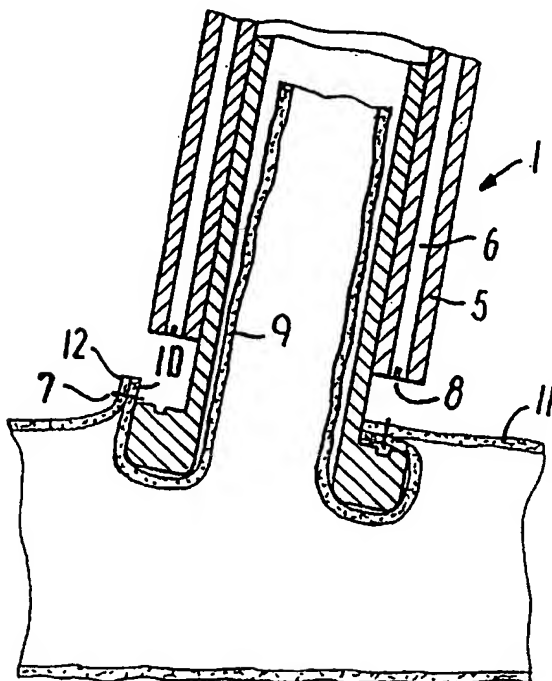


FIG. 7

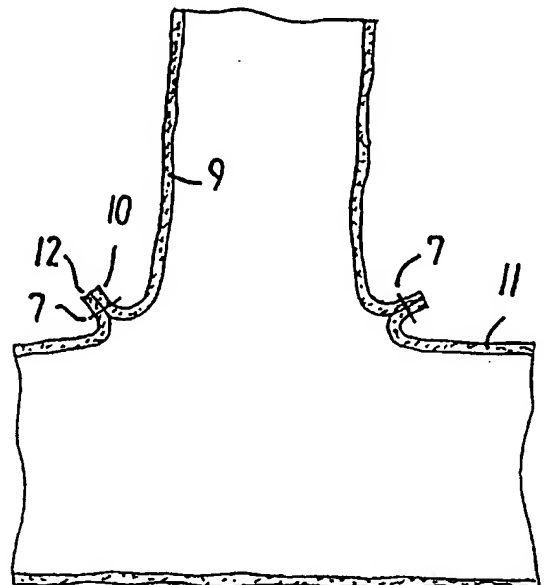


FIG. 8

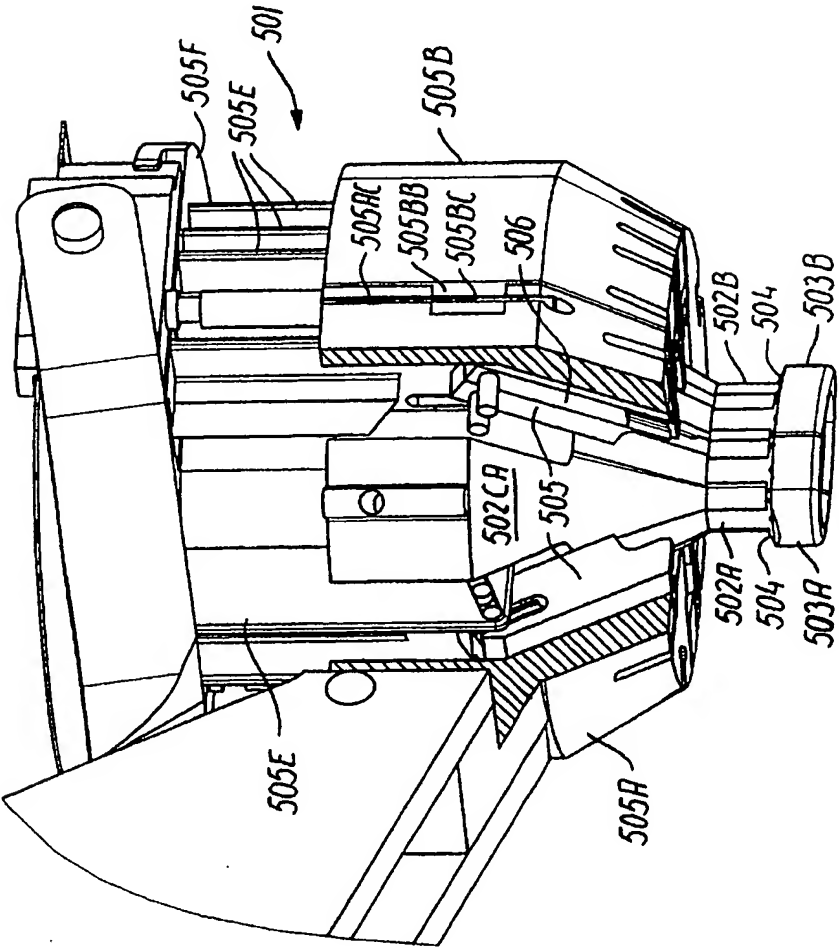


FIG. 9

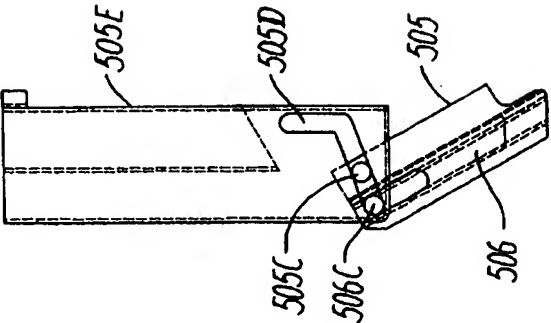


FIG. 12



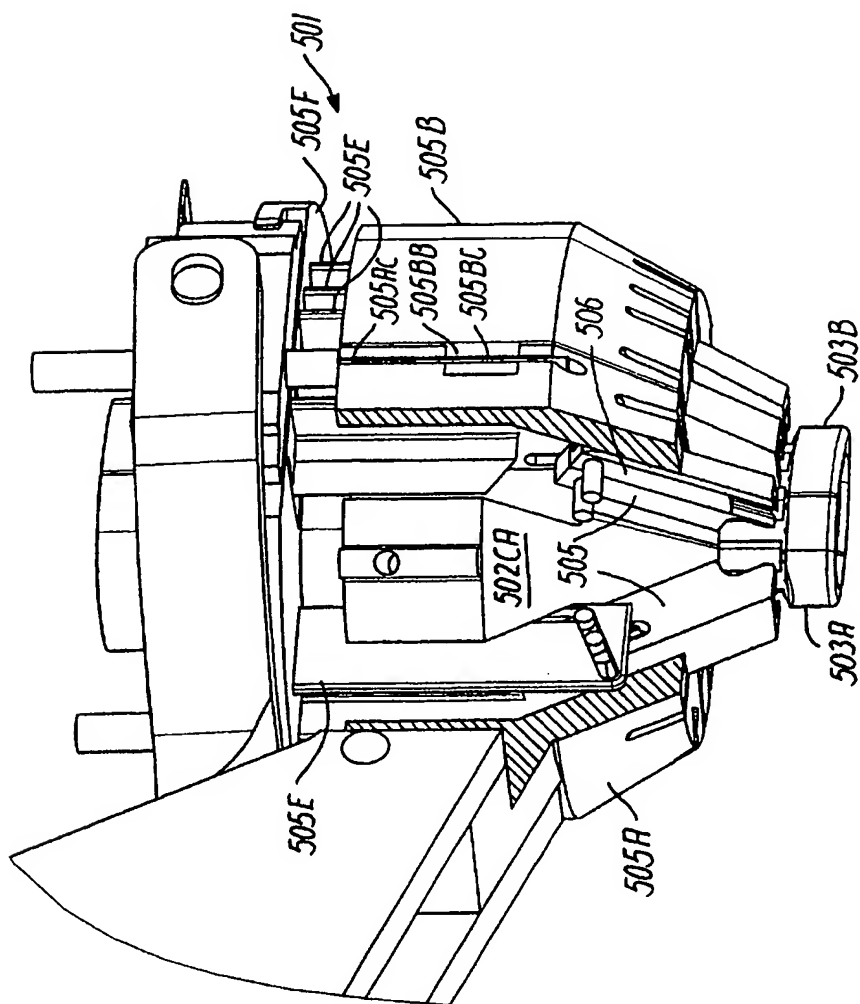


FIG. 10

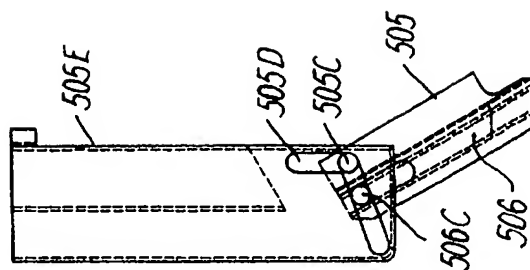


FIG. 13

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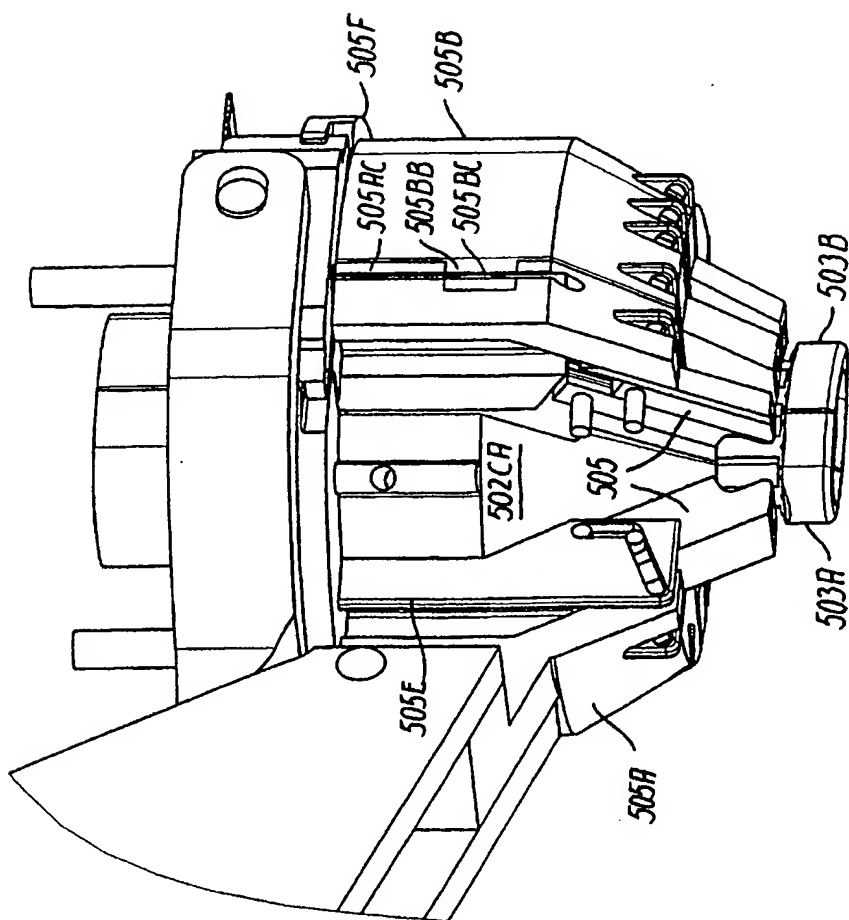


FIG. 11

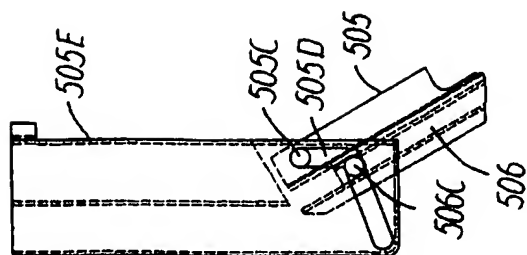
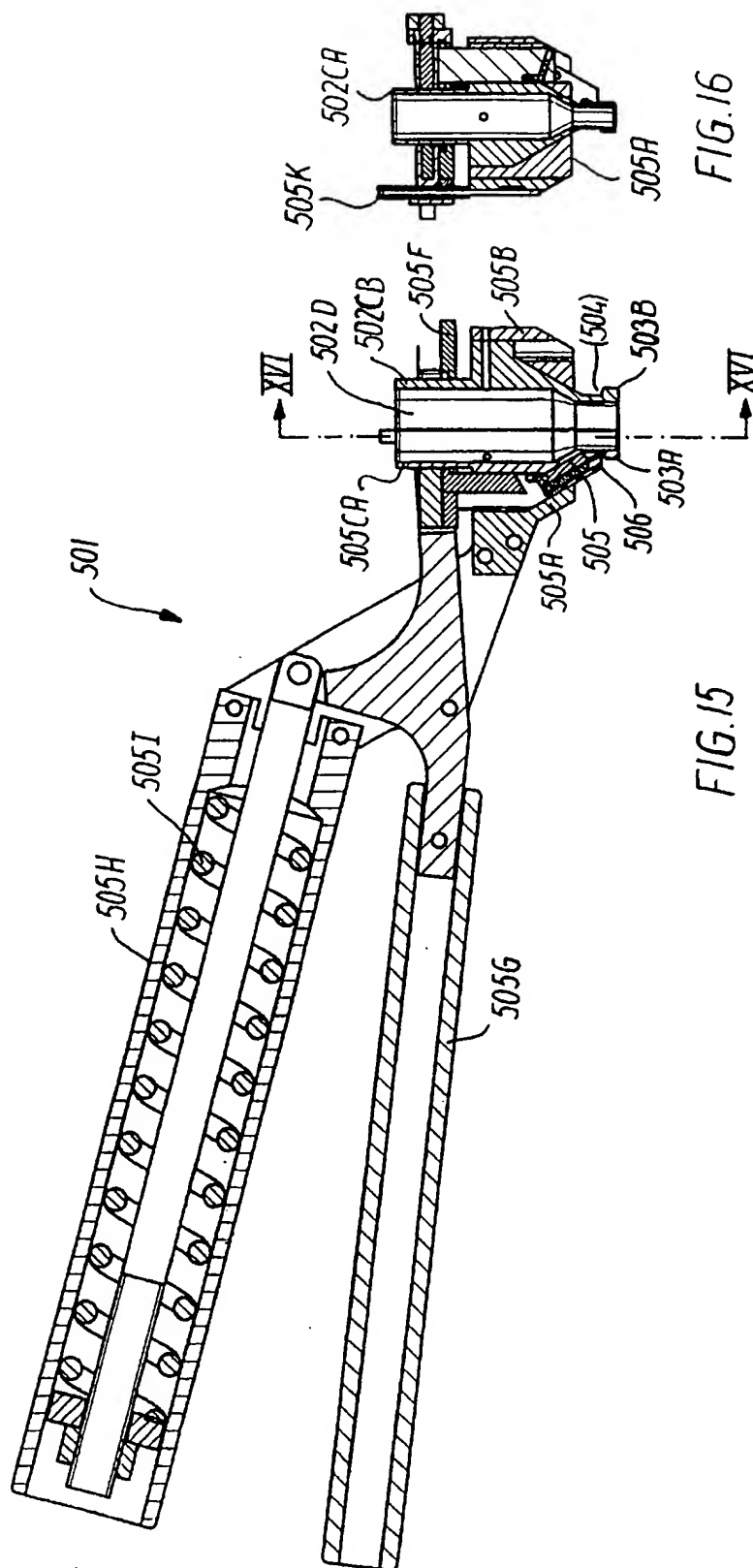


FIG. 14

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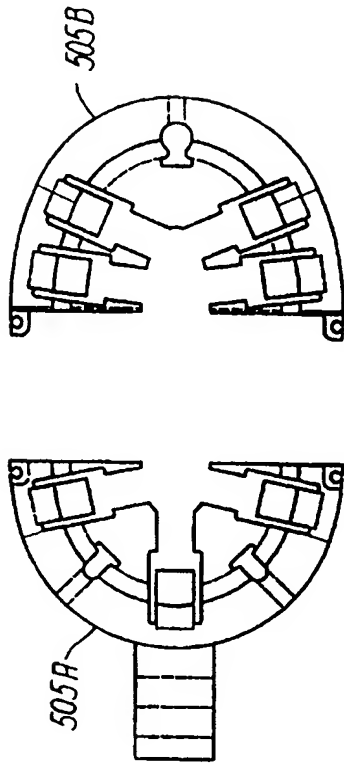


FIG. 20

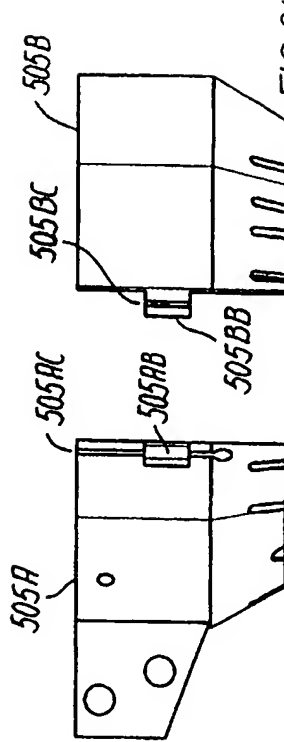


FIG. 21

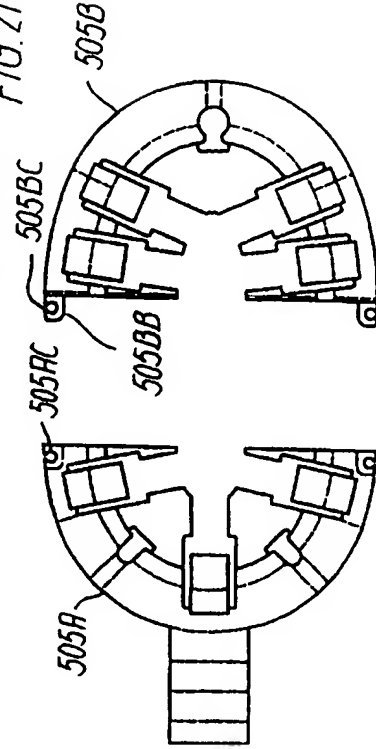


FIG. 22

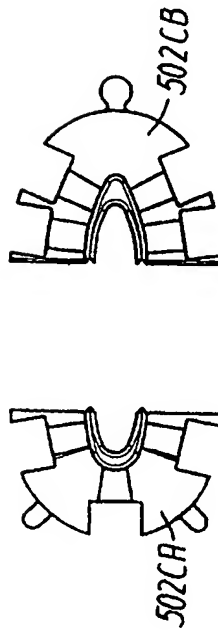


FIG. 17

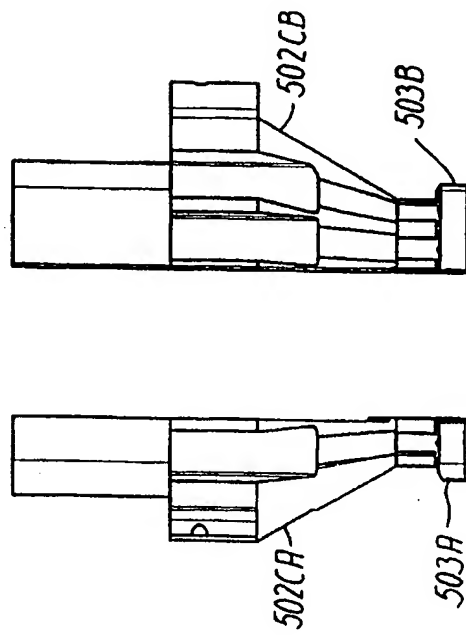


FIG. 18

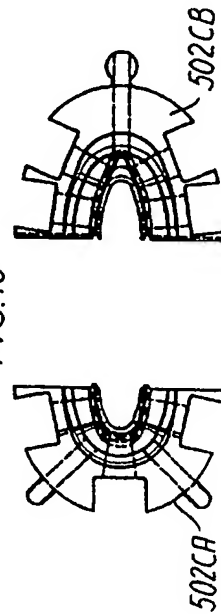


FIG. 19

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 96/00197

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/115

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5292053 A (F.BILOTTI ET AL.), 8 March 1994 (08.03.94), figure 5 --	
A	US 5205459 A (R.J.BRINKERHOFF ET AL.), 27 April 1993 (27.04.93), figure 5 --	
A	US 5119983 A (D.T.GREEN ET AL), 9 June 1992 (09.06.92), figure 2 -- -----	



Further documents are listed in the continuation of Box C.



See patent family annex.

- \* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

17 February 1997

Date of mailing of the international search report

20 -02- 1997

Name and mailing address of the ISA/

Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

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Anette Hall

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 96/00197

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-3  
because they relate to subject matter not required to be searched by this Authority, namely:

A method for treatment of the human body by surgery. This is subject matter which the International Searching Authority is not required to search under Article 17(2) (a) (i) and Rule 39 (iv).

2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
**PCT/DK 96/00197**

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US-A-	5292053	08/03/94	AU-B- 654371	03/11/94
			AU-A- 2109792	25/02/93
			CA-A- 2076602	24/02/93
			EG-A- 19853	31/05/96
			EP-A- 0536882	14/04/93
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			DE-U- 8714082	18/02/88
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			JP-B- 2538987	02/10/96
			JP-A- 63300751	07/12/88
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